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Research Paper

Adherence to Informed Consent and its Completeness in a selected Tertiary Care Hospital.

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ABSTRACT
Background: *The process of obtaining permission from a patient and their families to perform an operation, conduct a test, or begin treatment is known as informed consent. Patient-centred medical care requires informed consent. The* ***objective*** *was to assess compliance with the essential Components to be filled in the Informed consent for surgery in a tertiary care hospital and to analyse the deficiencies in informed consent for surgery.* ***Methods****: A survey was conducted at different surgical departments of a teaching hospital for 30 days from December 2022 to Jan 2023. A random active patient file was selected. All audit was based on the Defined checklist. Compliance with essential components of the surgery informed consent form was observed for post-surgery patients. collected data were entered in an Excel sheet on a daily basis to analyse the deficits with the essential components, and numbers of consent form compliance levels as shown in the graphs.* ***Results****: For this study, 80 surgery-informed consents and 75 anaesthesia-informed consents were chosen at random. In 95% of surgery consents, 93% of anaesthesia consents did not include the procedure name in capital letters, both consents did not include the procedure name in a full form about 31% of the time, surgery consent 97.50% did not include the time, and anaesthesia consent did not include the date and time as a consent form deficit. In both consents, the doctor's name, signature, and seal were present in excess of 80% of the time. The patient details in both consents were 100% full, while the other important component in both consents was more than 80% complete. The re-audit result after sensitization for some of the essential component completeness, on the other hand, was comparatively better.* ***Conclusion:*** *The quality of the existing informed consent process in a teaching hospital is very important. There is a great need to educate doctors and healthcare regarding the importance of patient's autonomy and their right to information about their medical condition and the proposed surgical procedures to ensure their participation in the decision-making regarding their treatment.*
KEYWORDS: *Informed consent completeness, essential components, information, Hospital*

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I. INTRODUCTION:

Informed consent is a process in which a competent patient is provided all relevant information about his ailment so that he can participate in making health-care decisions. According to Berg, J. W., et al. (2001) [1], an informed consent is widely regarded to involve a discussion of the nature of the procedure, acceptable alternatives to the planned intervention, and the relevant risks and benefits associated with the process[1]. It is essential that the patient comprehends the information given and that the consent supplied is voluntary. The patient's comprehension is just as crucial as the information supplied. As a result, the information presented should be in basic terms.

In developed nations, there has been a paradigm change in which an increasing number of patient's desire to be fully informed about procedural alternatives, risks, and advantages before deciding to undertake a surgical treatment as it supports the Quadrelli, S., et al. (2008) [2] study. Unfortunately, in our hospital practice, patients and their families are frequently given insufficient or incorrect information. The purpose of this study was to assess the existing practice of obtaining informed consent for preoperative emergency and elective surgical procedures in a tertiary care teaching hospital. Reason for choice of audit was, there were deficiencies discovered in filling essential components in the surgery informed consent due to a lack of information among newly professionals, interns, and postgraduates. It is a manifestation of patients' and their families' active

engagement in decision-making, as well as a means of respecting individual patients' autonomy. Patients are increasingly being included in health-care decision-making, particularly in the West. This shift has occurred mostly as a result of improved patient awareness of their rights as per Wear, S. (1992) &. Beauchamp, T. L.,et al. (2001).[3-4]. The patient has the option to be an informed participant in his or her health-care decisions. It is extremely beneficial in resolving legal concerns. It is the participant's obligation to educate them about the purpose of the operation, the procedures, the risks and advantages, and to obtain their consent before participating in the research, as well as to keep the patient informed. The surgery Informed consent essential Components Consists of Hospital No, Patient Name, Age/ Sex, Procedure name with capital Letter & Full Name of the procedure, Patient/ Guardian and Witness sign, Date & Time, Name & Sign of the Treating Doctor with seal, Language (Primary Language Kannada / English) used, that Patients/ Guardian Understands

II. OBJECTIVES:

1. To assess compliance with the essential Components to be filled in the Informed consent for surgery in a tertiary care hospital

III. MATERIAL AND METHODS:

3.1 Preparation & planning: Check lists were created based on the main components to be filled out in the informed consent form, and before beginning the audit, an official circular was distributed as a friendly reminder to refresh awareness and to call attention to newly hired professionals. Every day, a random patient file check was planned for patients who had surgery.

Study design: Retrospective

Study duration: 30 days – Dec-20th, 2022 to Jan 20th, 2023

Sampling – Random active patient file audit

Sample Size –

- Surgery Consent form -80
- Anaesthesia Consent- 75

3.2Scope: Among all surgery in patients in Tertiary Care Hospital

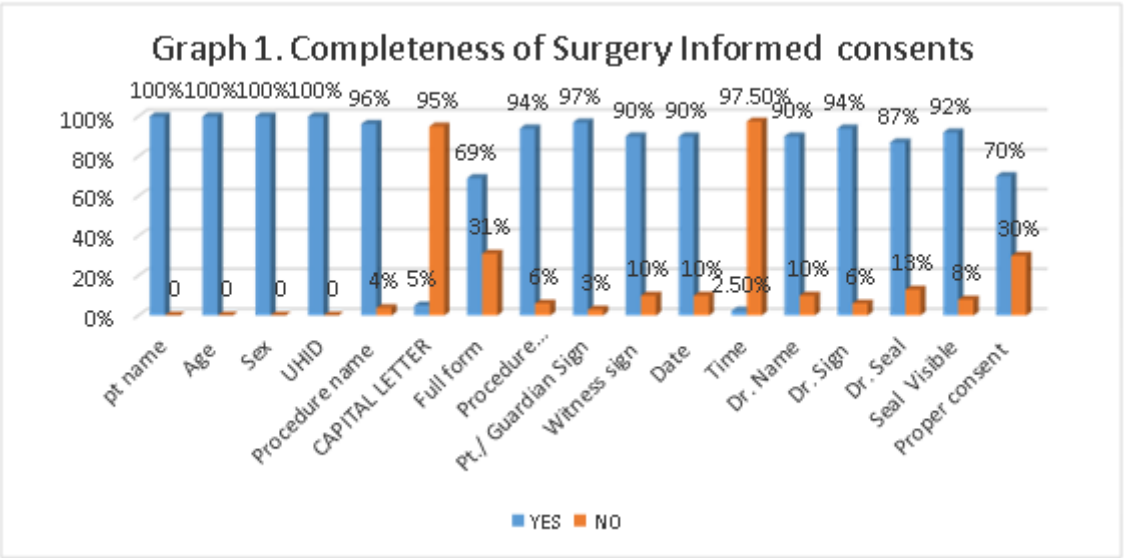
3.3 Inclusion criteria: Surgery and Anaesthesia Informed consents was included for the audit

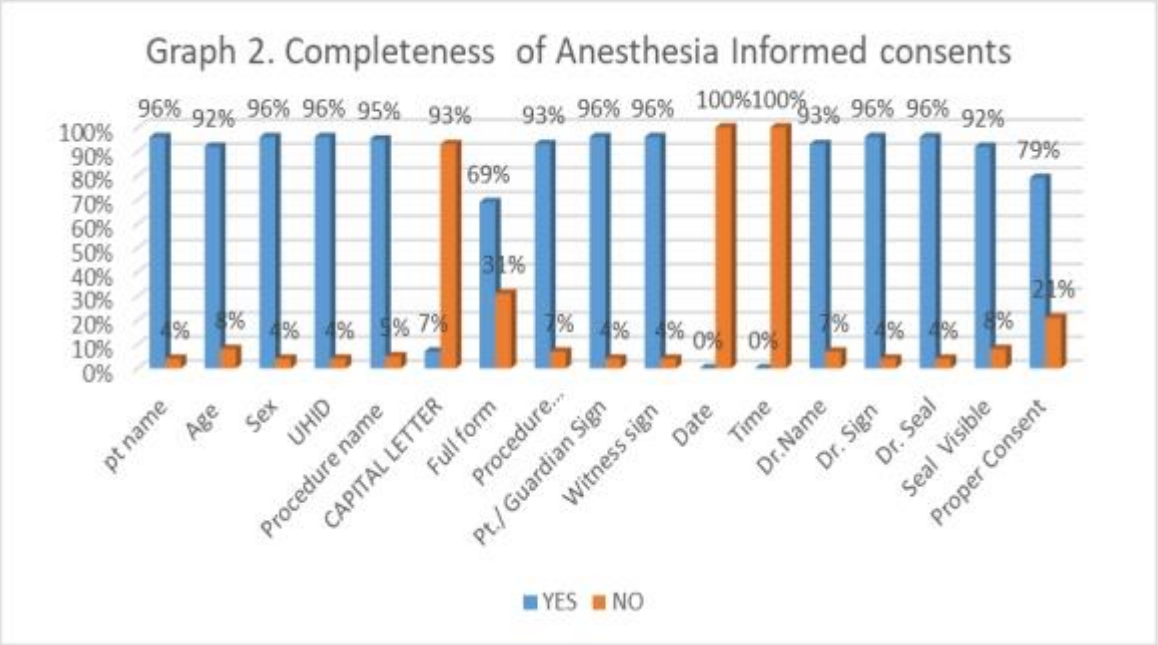
3.4 Exclusion criteria: All other consent forms such as ICU admission, blood transfusion, high risk, day care procedures and other consent forms were excluded

3.5 Data Collection: The observational assessment is conducted for all the Surgical Units at Tertiary Care Hospital. Compliance with essential components of the surgery informed consents form was observed for post-surgery patient. collected data were entered in an excel sheet on daily basis to analyses the deficits with the essential components, numbers of consent form compliance level as shown in the graphs**.**

IV. ANALYSIS &RESULTS:

Some essential components for filling out informed consents were overlooked, and illegible writing was discovered.





For this study, 80 surgery informed consents and 75 anaesthesia informed consents were chosen at random. In 95% of surgery consents, 93% of anaesthesia consents did not include the procedure name in capital letters, both consents did not include the procedure name in full form about 31% of the time, surgery consent 97.50% did not include the time, and anaesthesia consent did not include the date and time as a consent form deficit. In both consents, the doctors' name, signature, and seal were present in excess of 80% of the time. The patient details in both consents were 100% full, while the other important component in both consents was more than 80% complete as shown in the graph 1 & 2.

V. RESTRICTION OF THE AUDIT:

Consent forms itself without the minor essential components such as date and time. The date and time are given on the first page, but they are missing from the signing column. This confused the auditor. Sensitized the professionals to write in their own till the fresh supply of informed consent arrives.

The most common barrier to compliance with the surgery informed consent was a lack of knowledge and training for all cadres.

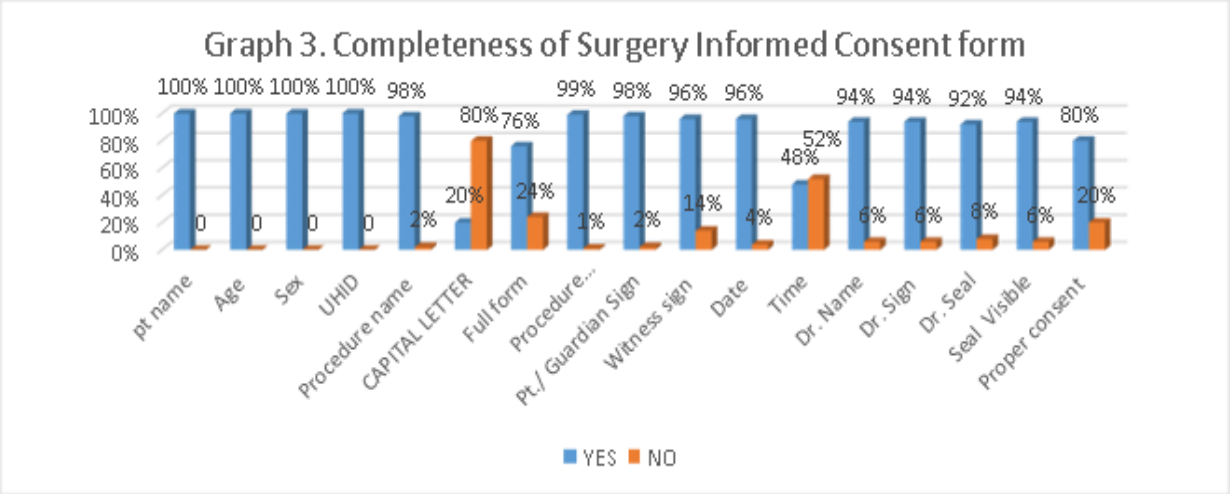
VI. CORRECTIVE ACTIONS:

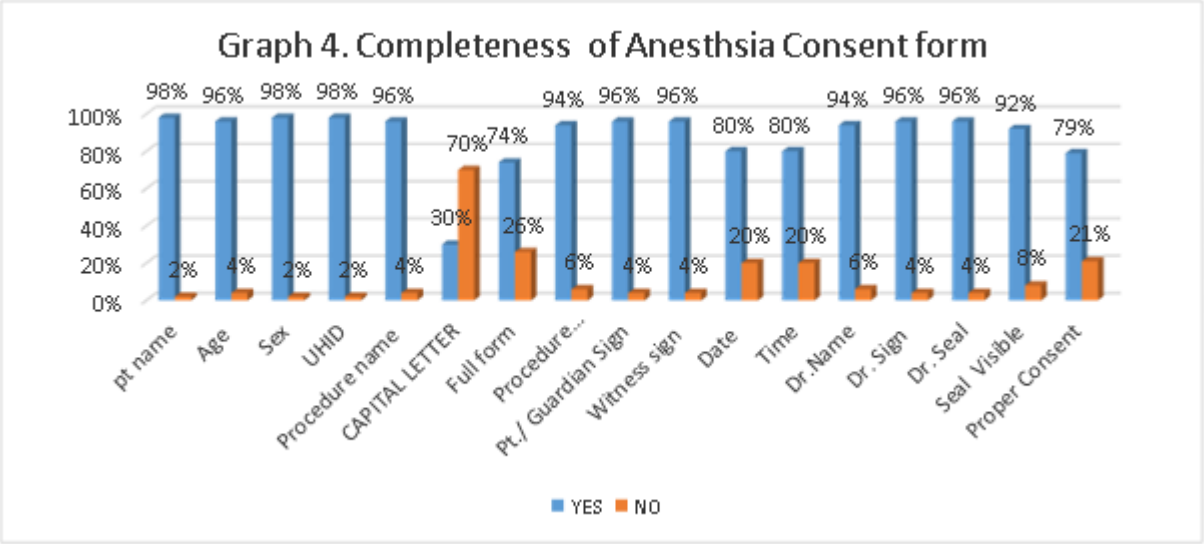
Sensitized all the department for completeness of the surgery informed consent form and other documentation. Active audit of the patient files has been started effectively and deficiencies communicated to the concerned departments.

Follow up & Evaluation of change: After the clinical audit for surgery informed consent is completed, the concerned department professionals who attended the departmental compliance level of documentation presentation, which was conducted by the Medical Record Section with the collaboration of the Quality cell team, have been sensitized to maintain the completeness of informed consent forms and other documentation to avoid deficiencies

After sensitization, the concerned department professionals agreed on compliance with all essential components of the surgery informed consent form, and the Continuous monitoring will be taken effectively for completeness of the documentation with continuous monitoring. With the greatest improvement in compliance may achieve and discover at the next audit.

VII. RE- AUDIT RESULTS:





According to the re-audit results, the procedure name in capital letters in surgical consent form 80%, anaesthesia consent form 30% met the compliance level, and both consents the procedure name in complete form more than 70% met the compliance level. Stating the time and date in both consents improved by more than 80%, and stating the doctors, name, sign, and seal improved by more than 90% in both consents. The patient information in both consents was totally compliant, as evidenced by the audit and re-audit results as shown in the graph 3 & 4.

VIII. DISCUSSION:

A variety of research publications that together offer a thorough understanding of the topic are consulted in the ongoing discussion on informed consent adherence and completeness in a particular tertiary care hospital. It is the patients' rights to know their treatment or any procedure by giving the consent, and it is also very important that informed consent be filled with all the essential information and it is required by law and medical ethics to obtain the informed consent of their patients before initiating treatment, including any surgical procedure[1]as per Berg, J. W., et al. (2001) [4]. In our study, we observed that 80 surgery informed consents and 75 anaesthesia informed consents were selected at random. Both consents did not include the procedure name in full form approximately 31% of the time, surgery consent did not include the time 97.50% of the time, and anaesthesia consent did not include the date and time as a consent form deficit. The doctors' name, signature, and seal were present in both consents more than 80% of the time. The patient information was 100% complete in both consents, whereas the other crucial component was more than 80% complete in both consents. Mudassir, H., (2006) [5], did a comparable study in which 71.5% and 45% of patients received information on

their medical condition and the nature of the suggested intervention, respectively[5]. According to Amin et al., only 15% of patients receive information on anaesthetic problems. Also as per Vessey et al.'s(1998) [6], study, while the majority of patients understood why an operation was planned, 28 out of 49 (57.1%) patients undergoing surgery for acute abdomen did not receive any information concerning the complications prior to surgery[5, 6]. According to our findings, in both surgery and anaesthesia consent form procedures and the complications explained to patients, the rate is greater than 90% in both the first and re audit. In one of other study done by Patil A et.al (2023) [7],nearly 15.8% of the patients who participated in the study were illiterate, whereas 35.3% had completed the eighth grade of secondary education. The patient's educational background is crucial during preoperative counselling and the Informed Consent process since patients could need assistance in understanding the medical jargon used by the treatment teams, including surgeons and anaesthesiologists[7] and study by Humayun A. et.al (2008) [8],Written and verbal agreement should be given in the local tongue. Even patients with limited education should be able to grasp the written consent forms. Each patient should be interviewed and examined in a private room to preserve informational and physical privacy, and the quantity of medical professionals should match the number of patients at any facility[8]. Our study looked into the language used on consent forms for patients and found that 80% of surgical consent forms and 79% of anaesthetic consent forms were properly employed and clarified which languages patients could understand. According to Yousuf RM, et.al (2007) [9],study findings support the idea that family dynamics and cultural background play significant roles in the process of getting informed consent. The findings highlight the necessity for doctors to adopt a new mind-set and recognise the patient's autonomy in a world that is fast changing by informing their patients of their rights and obligations as healthcare consumers. Then collaborative decision-making will be practical[9]. Our research mainly focused on the practise of obtaining and completeness informed consent by providing thorough information to the patients as printed in the consent in writing forms, as it supports the Yousuf RM et.al(2007) study Awareness, knowledge, and attitude regarding informed consent among doctors.According to a study by Chima SC et al,(2013) [9-10], there are a number of obstacles to the informed consent process, including language barriers, a dearth of interpreters, a heavy workload, and time restraints. Doctors spent 5 to 10 minutes on consent and gave patients the majority of the information they needed to know, but their understanding of key local regulations was insufficient[10]. Our study primarily focused on how doctors filled out informed consent forms, which indicates their practise of obtaining informed consent by giving the necessary information and counselling to the patients, as per our reassessment result, both surgery and anaesthesia informed consents were completed to a level of completion above 70%.

Through providing insights into the evolution, meaning, and current issues of informed consent, Beauchamp, T. L. (2011) [11], offers a historical perspective on the concept. Seeing informed consent via a historical perspective helps us better appreciate the challenges it faces now and how it has changed throughout time. Wear, S. (1998) [12], of informed consent in relation to professional beneficence and patient autonomy offers a theoretical foundation for comprehending the pertinent ethical issues. This source probably examines how to strike a careful balance between upholding a patient's autonomy and making sure that medical professionals behave in the patient's best interest.By highlighting the significance of good communication between healthcare providers and patients, Brody, H. (1989) [13], work on transparency in informed consent in primary care could further enhance the conversation. This reference could emphasize how important it is to have an honest and transparent consent process.Traditional ideas of informed consent are contested by King, J. S., & Moulton, B. W. (2006) [14], proposal for shared medical decision-making, which promotes a more cooperative strategy. In order to promote a more patient-centred approach, this viewpoint presents the notion that consent should be a joint agreement between patients and healthcare practitioners.In addressing the important topic of what patients need to know to make informed decisions about their treatment, Murray, B. (2012) [15], review of what doctors must tell patients [15] probably goes into detail on information disclosure in the informed consent process.The analysis of legal and ethical myths surrounding informed consent by Meisel, A., &Kuczewski, M. (1996) [16], may offer important new perspectives on widespread misunderstandings that could influence the observance of informed consent procedures. Any misconceptions that can jeopardise the integrity of the consent procedure might be found and cleared up with the use of this reference.A thorough grasp of the idea is probably provided by Faden, R. R., & Beauchamp, T. L. (1986) [17], historical and theoretical viewpoint on informed consent, which traces the concept's development and presents a theoretical foundation. This resource might help to advance a more thoughtful understanding of the tenets and foundations of informed consent.A note of caution is added by O'Neill, O. (2003) [18], exploration of the bounds of informed consent, which highlights the moral precipices and potential difficulties surrounding informed permission. This reference might cause one to reflect carefully on the boundaries that need to be acknowledged in the process of gaining informed consent.Grady, C. (2015) [19], analysis of the persistent and new issues surrounding informed consent offers a modern viewpoint and clarifies how informed consent is changing in the context of modern healthcare. This reference could be very helpful in addressing the changing difficulties that healthcare providers encounter when trying to get meaningful consent.The clinical practice primer by Bowman, D., Spicer, J., & Iqbal, R. (2011) [20] probably offers useful advice on how to apply informed consent in typical healthcare situations. This source could be a

useful manual for medical professionals, providing useful suggestions for improving the comprehensiveness of informed consent.Together, the provided references offer a comprehensive framework for the consideration of informed consent adherence and completeness in tertiary care hospitals. These publications' scientific results, historical background, ethical considerations, and useful insights all add to a thorough and well-informed investigation of the subject.

IX. RECOMMENDATIONS:

To be more specific, the primary goal of the study shall be included patients and clinicians who are involved in obtaining informed consents.

X. CONCLUSION:

However, the study outcome of both audit and re audit is greater than 70% compliance level obtained towards completeness of necessary components while getting informed consents from patients for their surgery and its universal challenges in healthcare sectors. There is still a tremendous need to Sensitize Health-care providers on the necessity of getting informed consents and their completeness in order to enrich practise and improve doctors' positive attitudes, as well as to achieve a higher level of compliance.

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